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International Business Machines Corporation  
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Charlotte, NC 28262-4333

EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/629,448	<b>Applicant(s)</b> KELKAR ET AL.	
	<b>Examiner</b> Lori A. Clow, Ph.D.	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-16 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/6/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### **Election/Restrictions**

Applicant's election with traverse of Group I, claims 1-6, 10-16, and 20 in the reply filed on 7 April 2006 is acknowledged. The traversal is on the ground(s) that inventions I and II are classified in the same class. This is not found persuasive because, as noted in the requirement for restriction, the inventions contain vastly different method steps with different stated outcomes. Therefore, the inventions have different effects.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-9 and 17-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7 April 2006.

### **Information Disclosure Statement**

The Information Disclosure Statement filed 6 October 2003 has been considered. A signed copy of PTO Form 1449 is included with this Office Action.

### **Drawings**

The Drawings submitted 29 July 2003 are accepted.

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### **Specification**

The disclosure is objected to because of the following informalities: On page 14, line 10 of the Specification, reference is made to Table III. However, there is no Table III disclosed.

Appropriate correction is required.

The use of the trademark Intelligence Miner<sup>TM</sup> has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### **Claim Rejections - 35 USC § 101**

#### ***Non-Statutory Subject Matter***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The method of the instant claims is directed to determining functional similarity between portions of gene expression profiles. The method comprises steps in which gene expression profiles are processed, listed, and clustered, in silico. The claims, as a whole, do not produce a result which is concrete, tangible, and useful. The claims merely encompass in silico data about statistical distributions of expression profiles with no **specific** output that meets the concrete, tangible, and useful criteria. No **specific** outcome is set forth in the claims such that the steps of

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the method produce a result that is immediately concrete, tangible, and useful. The claims must, as a whole, satisfy section 101 and must be for practical application, which can be defined as:

1. The claimed invention “transforms” and article or physical object to a different state or thing.

*[The claimed invention in the instant case does not transform any physical object or article. The listing of clusters does not meet the criteria a physical transformation of the instant method steps.]*

2. The claimed invention otherwise produces a useful, concrete, and tangible result, based upon various factors (see below) *[The claimed invention in the instant application does not produce a concrete, tangible, and useful result]*.

It is further noted that “the focus of the inquiry is whether the claim, considered as a whole, constitutes ‘a practical application of an abstract idea.’” State Street, 149 F.3d at 1373, 47 USPQ2d at 1600. Thus, the question of whether a claim encompasses statutory subject matter should not focus on which category of subject matter a claim is directed (e.g. process or machine), “but rather on the essential characteristics of the subject matter, in particular its practical utility.” State Street, 149 F.3d at 1375, 47 USPQ2d at 1602; see also AT&T, 172 F.3d at 1360, 50 USPQ2d at 1453.

#### Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application.” AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” (1) “USEFUL RESULT” For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO’s official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and Fisher, 421 F.3d at \_\_\_, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of “specific” and “substantial”). (2) “TANGIBLE RESULT” The tangible requirement does not necessarily mean

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that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had “no substantial practical application.”). “[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection.” Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 (“It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .”). In other words, the opposite meaning of “tangible” is “abstract.” (3) “CONCRETE RESULT” Another consideration is whether the invention produces a “concrete” result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is “irreproducible” claim should be rejected under section 101). The opposite of “concrete” is unrepeatable or unpredictable.

Applicant is invited to view the following web site for the text of the new Interim

Guideline guidelines of November 2005:

[http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101\\_20051026.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf)

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 10-16, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able to determine **functional** similarity between portions of gene expression profiles. For the reasons discussed below, this constitutes undue experimentation.

b) The specification provides discussion regarding the advantage of the invention to determine functional similarity between portions of gene expression profiles to characterize similarity between genes in one or more phases of the cell cycle (page 3). The specification teaches a program product by which the logic means has a clustering section which lists gene expression pairs in clusters by their match fractions. For example, if gene  $g_i$  is similar to gene  $g_j$ , then these two genes are placed in a cluster  $c_a$  and  $i$  and  $j$  are added to the gene index array  $G$  and to the cluster index array  $C$ . The next gene expression pair  $g_i$  and  $g_k$  are then examined. If gene  $g_i$  is similar to gene  $g_k$ , but  $i$  and  $k$  are already in the gene index array  $G$  then the next gene expression pair is examined. But if gene  $g_i$  is in the index  $G$  but gene  $k$  is not, then gene  $k$  is placed in cluster  $c_a$  with  $i$  and  $j$  by adding  $k$  to  $G$  and to  $C$ . The specification teaches further embodiments of distinguishing gene clusters based upon match fractions.



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However, the specification does not teach a method of determining **functional** similarity between portions of gene expression profiles, as claimed in the instant invention. There are no parameters set forth in the specification that would guide one of ordinary skill in the art to determine functional similarities in gene expression profiles. There are no correlations set forth that would distinguish functional similarities based upon cluster assignment. There is no meaning associated with a gene belonging to one cluster or another in terms of functionality. Therefore, one of skill in the art would not know how to use the invention and the claims are not enabled.

c) The specification provides working examples of using the particular method to determine gene clusters only.

d) The invention is drawn to methods of determining functional similarities between portions of gene expression profiles. However, no such teaching of how to perform the method for this determination is disclosed.

e) and g) It would have been well known in the art that clustering to determine gene expression profiles can determine membership of genes to similar classes, based upon similar expression patterns or to find similar sequences in a set. For example, Agrawal et al. (Proceedings of the 21<sup>st</sup> VLDB Conference, Zurich, Switzerland, 1995, pages 1-12) teach a model of similarity of time sequences that consider sequences similar if they have enough overlapping time-ordered pairs of subsequences that are similar.

The instant specification, however, does not elucidate how one of skill in the art would use the disclosed clustering method for the determination of **functional** similarity between gene expression profiles.



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f) The skill of those in the art of molecular biology and bioinformatics is high. However, absent a teaching in the instant specification for how to use the clustering method to determine functional similarity, the claims are not enabled.

h) The claims are broad because they are drawn to determining functional similarity in gene expression profiles, without any steps that actually identify functional similarity. The skilled practitioner would first turn to the instant specification for guidance to practice such methods. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that clustering may be used to assign genes to groups based upon patterns of expression only. Finally, said practitioner would turn to trial and error experimentation. Such represents undue experimentation.

### **Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 10-16, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 10, and 20 recite “a method for determining functional similarity between portions of gene expression profiles” or “a program product” for performing the same. However, there is no step in the claim of actually determining a functional similarity. Clarification is requested.

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**Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

June 7, 2006

Lori A. Clow, Ph.D.

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*Lori A. Clow*  
*Patent Examiner*